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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/029,423 | 12/20/2001 | R. Forrest Waldon | 8789-21 | 3708 |

20792 7590 06/25/2003

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EXAMINER

WELLS, LAUREN Q

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 06/25/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/029,423

Applicant(s)

WALDON ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 17-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5. 6) ☐ Other:

DETAILED ACTION

Claims 1-51 are pending. Claims 17-51 are withdrawn from consideration, as they are directed toward non-elected subject matter.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a composition, classified in class 514, subclass 171.
- II. Claims 17-51, drawn to a method of treating female sexual dysfunction, classified in class 514, subclass 874.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to treat baldness in men by topical application of the composition to the bald/balding spot. Alternatively, the process can be practiced with another product, such as a composition comprising a phosphodiesterase inhibitor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

-an estrogenic compound

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-an androgenic compound

-a vasodilation compound

-a progestin

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-51 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Jarett Abramson on 6/2/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16, wherein 17B-

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estradiol (estrogenic), oxandrolone (androgenic), phentolamine hydrochloride (vasodilator), and megestrol acetate (progestin), were elected as the species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase “administered on a performance on demand basis” in claim 16, lines 6-7, is vague and indefinite, as it is confusing. What does it mean to administer a certain component of a composition on a performance on demand basis? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. (6,284,263) in view of Estok (6,011,043).

The instant invention is directed toward a composition comprising an estrogenic compound, an androgenic compound, and a vasodilation compound, all in therapeutically effective amounts, and a pharmaceutically acceptable carrier.

Place et al. ('263) exemplify a composition comprising testosterone, estradiol, progesterone, and carrier. Oxandrolone is taught as interchangeable and combinable with testosterone. 17B-estradiol is taught as a preferred estradiol. Megestrol acetate is taught as interchangeable and combinable with progesterone. The composition is specifically taught for improving vaginal muscle tone and tissue health and for enhancing vaginal lubrication. The reference lacks a vasodilator and apomorphine. See Col. 3, line 66-Col. 4, line 4; Col. 13, line 40-Col. 14, line 47; Col. 15, line 28-Col. 18, line 37.

Estok teaches a combination of phentolamine and apomorphine for the treatment of human sexual function and dysfunction, such as female sexual dysfunction. Phentolamine hydrochloride is taught as a specific form of phentolamine. The composition is specifically taught for treating orgasmic dysfunction due to clitoral irregularities or disturbances. See Col. 1, lines 50-58; Col. 4, line 65-Col. 6, line 15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the composition of Estok to that of Place et al. because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third

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composition that is to be used for the very same purpose. In *re Kerkoven*, 205 USPQ 1069 (CCPA 1980). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the composition of Estok to that of Place et al. because of the expectation of more potently treating female sexual dysfunction by additionally treating orgasmic dysfunction.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use of the composition is not given patentable weight, i.e., the phrases “for treating female sexual dysfunction”, “administered on a performance-on-demand basis”.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
June 18, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

6/24/03